Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Medical Test Site Rule Changes

by Susan Walker, DOH

The intent of the Medical Test Sites (MTS) Law, Chapter 70.42 RCW, is to meet the requirements of federal laws licensing and regulating medical laboratory testing (CLIA). The state MTS law and rules, Chapter 246-338 WAC, have been approved by the federal government and granted an exemption from CLIA.

On January 24, 2003, changes to the CLIA regulations were published in the Federal Register. These changes went into effect in April 2003. Following a federal review of the state MTS rules, changes are necessary to bring the rules into compliance with the CLIA regulations. The changes to the MTS rules incorporate the changes that were made in the CLIA regulations, along with additional housekeeping changes. This will allow the state to continue its exemption from federal regulation for sites performing clinical laboratory testing.

The changes include definition updates, quality control provisions, personnel qualifications, patient test management requirements, quality assurance requirements and consensus required for grading proficiency testing challenges. A copy of the changes is available on the Department of Health, Laboratory Quality Assurance webpage: www.doh.wa.gov/hsqa/FSL/lqa_updates.htm. The CLIA regulations are available at: www.phppo.cdc.gov/clia/regs/toc.aspx.

The following article is a summary of the changes to the MTS rules. The Notice announcing the effective date of the changes is found on page 5. Copies of the new WAC will be available on the LQA website once the WAC implementation process is complete. Information about how to obtain a copy of the revised WAC will be published in a future edition of this newsletter.

NOTE: The MTS rule changes will <u>not</u> affect licensees who hold a Certificate of Waiver or a Provider Performed Microscopic Procedures (PPMP) license.

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

- Anemia
- ANA
- Bioterrorism Event Mgmt
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Hepatitis
- HIV
- Infectious Diarrhea
- Intestinal Parasites
- Lipid Screening
- Point-of-Care Testing
- PSA
- Rash Illness
- Red Cell Transfusion
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

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WAC 246-338-010 Definitions

- "Calibration verification" – changed wording in the definition from assaying of calibration materials to assaying of materials of known concentration;
- "HCFA" changed to "CMS" – Centers for Medicare & Medicaid Services;
- Changed references to moderate and high complexity testing to nonwaived, consistent with CLIA;
- Added a defintion for HHS, Department of Health and Human Services;
- "Subspecialty" – updated subspecialty categories to eliminate "other chemistry", "other hematology" and "other immunohematology"; changed blood group to ABO Grouping and crossmatching to compatibility testing;

WAC 246-338-028 On-site inspections

- "HCFA" changed to "CMS" – Centers for Medicare & Medicaid Services;

WAC 246-338-040 Approval of accreditation organizations

- "HCFA" changed to "CMS" – Centers for Medicare & Medicaid Services;

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WAC 246-338-050 Proficiency Testing

- Replaced HCFA with HHS as the entity that approves proficiency testing programs;
- Changed ABO group and D(Rh) to ABO grouping and Rh typing;
- More PT samples will be graded by the PT programs because the percentage for agreement among laboratories for grading purposes was modified in the CLIA regulations;

WAC 246-338-060 Personnel

- Eliminated the language regarding the grandfather clause for persons that passed an exam for director conducted by United States Public Health Service prior to July 1, 1970, as this is part of the CLIA personnel standards which are cross-referenced (42 CFR Part 493 Subpart M);
- CLIA personnel regulations now require all new PhD directors of high complexity testing to be certified by an approved board. A list of approved boards is available at: http://cms.hhs.gov/clia/dirclcon.asp.

WAC 246-338-070 Records

(1) Requisitions
- (a) Changed specimen identification to read patient identification;
- (b) Added address to information needed to identify person ordering the test;
- (f) Added age or date of birth
- (g)(ii)(B) Changed wording for PAP smear requisitions: Indication whether the patient ~~has history of cervical cancer or its precursors~~ had a previous abnormal report, treatment, or biopsy;

(2) Test Record Systems
- (b)(ii) Added the time to the information needed for when the specimen was received;

(3) Test Reports
- (c)(ii)(v) Added additional language that must be included: Patient's name and identification number, or a unique patient identifier and identification number; specimen source, when appropriate;

(4) Cytology Reports
- (b) Updated reference to the 2001 Bethesda system of terminology;

(6) Cytogenetics Reports
Revised language:
- (a) Use the International System for Cytogenetic Nomenclature;

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- (b) Include the number of cells counted and ~~karyotyped~~ analyzed;
- (c) Include a summary and interpretation of the ~~karyotypes findings~~ observations;

Added language:

(8) Storage of records, slides, and tissues must be done under storage conditions that ensure proper preservation;

(9) If the medical test site ceases operation, it must make provisions to ensure that all records and, as applicable, slides, blocks and tissue are retained and available for the time frames specified in Table 070-1.

Table 070-1(d)(e)

- Added oral pathology to the section of histopathology to clarify that the requirements for specimen blocks, reports, and stained slides pertain to oral pathology as well as histopathology;

WAC 246-338-080 Quality Assurance

Added/revised language:

- (1)(a)(i)(B) QA plan must include policies and procedures to monitor, evaluate, and review proficiency testing results, and test results, including biannual verification of tests that are covered by proficiency testing but have unsatisfactory scores, are not scored by the proficiency testing program, or where scoring does not reflect actual test performance (e.g., the proficiency testing program does not obtain the agreement required for scoring);

- (1)(f) QA plan must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

- (2)(h)(i) QA plan must include mechanisms or systems to ensure that specimens are properly labeled, including patient name or unique patient identifier and, when appropriate, specimen source; and ensure confidentiality of patient information throughout all phases of the testing process;

- (4)(a)(b) When control or calibration materials fail to meet the established criteria for acceptability, the MTS must have a system in place to determine if patient test results have been adversely affected. This must include a review of all patient test results obtained in the unacceptable test run; and a review of all patient test results since the last acceptable test run.

- (6)(b) Ensure that molecular amplification procedures that are not contained in closed systems have a unidirectional workflow. This must include separate areas for specimen preparation, amplification and production detection, and as applicable, reagent preparation;

- (6)(c) The owner must establish, ~~post~~ make accessible, and observe safety precautions;

WAC 246-338-090 Quality Control

Revised language:

- (4) For quantitative tests, the medical test site must perform quality control as follows:
  - (a) Include two reference materials of different concentrations each day of testing unknown samples, if these reference materials are available; or
  - (b) ~~Have an equivalent mechanism to assure the quality, accuracy, and precision of the test if reference materials are not available~~ Follow an equivalent quality testing procedure that meets federal CLIA regulations.

- (5) For qualitative tests, the medical test site must perform quality control as follows:
  - (a) Use positive and negative reference material each day of testing unknown samples; or
  - (b) ~~Have an equivalent mechanism to assure the quality, accuracy, and precision of the test if reference materials are not available~~ Follow an equivalent quality testing procedure that meets federal CLIA regulations.

- (6) The medical test site must:
  - (g) Rotate control material testing among all persons who perform the test;
  - (h) Use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system, if using calibration material as a control material;

- (7)(a)(b) Changed the requirement for calibration verification to apply to both moderate and high complexity tests; added language for validation of

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moderate complexity testing that if the lab uses the reference range provided by the manufacturer, they must verify that it is appropriate for their patient population;

- (9) Added language for all specialties that the laboratory must follow specialty quality control requirements or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-1 General Quality Control Requirements

- Added immunohistochemical stains to types of stains that must have positive and negative controls run each time of use;

- **Table 090-2 Quality Control Procedures**
  Consolidated requirements for calibration verification for moderate and high complexity testing into one table;

- **Table 090-3 Quality Control Procedures - Chemistry**
- Revised the language for quality control for blood gases:
  - Calibration — Follow manufacturer's specifications and frequency
  - ~~Two-point calibration and~~ One level of control ~~reference~~ material — Each 8 hours of testing, using both low and high values on each day of testing
  - One-point calibration or one control ~~reference~~ material — Each time patient sample is tested, unless automated instrument internally verifies calibration every 30 minutes
  - ~~Another calibration and reference material schedule , approved by the department~~

Table 090-4 Quality Control Procedures - Hematology

- Changed the frequency for running quality control for automated hematology instruments from every eight hours to each day that patient samples are tested;

Table 090-6 Quality Control Procedures – General Immunology

- Changed the QC requirements for test kits with procedural (internal) controls to require positive and negative external controls when the kit is opened; and each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Syphilis Serology 090(9)(e)

- Changed the requirement for testing positive and negative reference materials with each test run to each day of testing;

Tables 090-7 & 8 Quality Control Procedures – Bacteriology & AST

- Changed the QC requirements from each day or week of use to each batch, shipment and new lot number for catalase, coagulase, oxidase, beta-lactamase Cefinase reagents, bacitracin, optochin, ONPG, X and V disks or strips;
- Changed acid-fast stain QC from each week of use to each day of use;
- Changed antisera QC from each month of use to every six months;
- Changed the QC requirements for test kits with procedural (internal) controls to require positive and negative external controls when the kit is opened; and each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations.
- Updated NCCLS references;

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Table 090-9 Quality Control Procedures – Mycobacteriology

- Revised language to read that QC for all reagents or test procedures used for mycobacteria identification must be done using an acid-fast organism that produces a positive and negative reaction each day of use, unless otherwise specified;
- Changed acid-fast stain QC requirements to a positive and negative each day of use;
- Changed fluorochrome acid-fast stain QC to each time of use;
- Clarified that each batch of media, and each shipment lot of antimycobacterial agents used for susceptibility testing must have QC performed before or concurrent with initial use;

Table 090-10 Quality Control Procedures – Mycology

- Added: QC for lactophenol cotton blue stain must be done each batch or shipment and each lot number;
- Changed the QC requirement for acid-fast stains from each week to each day of use;
- Changed QC for reagents for biochemical and other identification test procedures from each week of use to each batch or shipment and lot number;

Cytology (090)(9)(h)

- (ii)(B) Revised language: Technical personnel must examine, unless federal law and regulation specify otherwise, no more than one hundred cytological slides ~~by nonautomated microscopic technique~~ (one patient specimen per slide; gynecologic, nongynecologic, or both) in a twenty-four-hour period and in no less than an eight-hour work period;
- (ii)(D) Clarified that when counting slides for the 100 slides/day limit that each nongynecologic slide preparation made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide area may be counted as one-half slide;
- (iii)(D) Added language that records of initial examination and rescreening results are available and documented;
- (iii)(G) Changed the requirement for correlation with histopathology reports of all abnormal cytology reports to all HSIL, adenocarcinoma, or other malignant neoplasms;

Immunohematology/Transfusion Services (090)(9)(i)

- Updated FDA citations;

Histocompatibility (090)(9)(j)

- Updated CLIA cross-reference 42 CFR Part 493.1278

Cytogenetics (090)(9)(k)

Revised language:

- (i) Document:
  (D) Reactions observed;
  (F) Sufficient resolution ~~to support the reported results~~ appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided
- (iv) Perform ~~confirmatory testing on all atypical results when performing~~ full chromosome analysis for determination of sex ~~by X and Y Chromatin counts~~;

Medical Test Site Rule Change Effective Date

The Washington State Code Reviser form CR-103 will be filed on February 16, 2005, to allow for implementation of the revised Medical Test Site (MTS) rules outlined on the previous pages of this issue of Elaborations. The final version of the MTS rules will be published on March 2, 2005, and effective on March 19, 2005.

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Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/EHSPHL/PHL/train.htm)

Advanced Blood Cell Morphology
March 17 Shoreline

Parasitology Part III: Trichrome Stains
March 23 & 24 Shoreline

2005 WSSCLS/NWSSAMT Spring Meeting
April 28-30 Spokane

Northwest Medical Laboratory Symposium
October 26-29 Seattle

12th Annual Clinical Laboratory Conference
November Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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